CORRECTIVE ACTIONS

1. SCOPE

This procedure describes a systematic approach to identify existing causes of nonconforming testing or other quality problems related to the testing activities conducted by the Bureau of Laboratories within the State Laboratory Institute (SLI). This procedure also applies to complaints and quality problems identified in departments that support the testing activities of the Bureau of Laboratories.

2. OBJECTIVES

This procedure applies a systematic approach to identifying and eliminating problems to enhance opportunities to improve processes within the Quality System, by the implementation of effective corrective actions.

3. RESPONSIBILITY

It is the responsibility of the Quality Assurance Director and/or the Quality Assurance Manager to assure that this procedure is followed and updated as required.

4. RELATED DOCUMENTS

- Corrective Action Form (IPQA071)

5. PROCEDURE

A. DISCOVERY OF NONCONFORMITIES

The identification of the nonconforming work, problems with the quality system or with the testing activities can occur at various places within the Quality System. Nonconformities are documented using a corrective action form (IPQA071).

A routine analysis of quality data is made by the respective department supervisor to assess whether nonconforming testing is being produced or other quality problems are occurring within the Quality System. The Quality Assurance Director and/or the Quality Assurance Manager also conducts a

monthly review of the quality data to assess nonconforming testing and other quality problems.

Quality data includes, but is not limited to, information from: processes, incident/problem logs, work operations, concessions, internal audits, quality records including testing results, service reports, complaints, proficiency testing, chronic user errors, management review, staff observations, and other sources of quality data.

Appropriate statistical methodology is employed where feasible to detect recurring quality problems.

The Quality Assurance Director decides if further investigation is needed to identify the existing causes of the nonconformance or quality issues and initiates the completion of the Corrective Action Report Form (IPQA071). The Quality Assurance Manager distributes Form IPQA071 with an assigned identification number to the respective department.

A summary of the nonconformance or quality problem is documented in section 1 of form IPQA071 by the designated department and/or the QA Manager.

Complaints are considered potential quality nonconformance and are handled as testing conformances and quality problems.

B. Root Cause Analysis

Root causes and/or potential causes of testing nonconformances or other quality problems are investigated by the respective department supervisor, appropriate staff and the Program Director and recorded in section 2 of IPQA071.

In cases where the potential cause is not clearly identifiable, careful analysis of all potential causes are analyzed, including sample requirements, sample specifications, methods and procedures, staff training and skill, consumables, equipment, calibration, etc...

C. Selection of Corrective Action(s)

If a root cause or potential root cause is identified, the Department Supervisor, appropriate staff, and the Program Director design a corrective action plan to eliminate the problem to prevent recurrence. The corrective action plan must be documented in section 3 of IPQA071 and:

- Contain acceptance criteria to assess the effectiveness of the plan
- Be communicated to the respective department to reach a mutual agreement on the schedule of its implementation.
- Be submitted to the Quality Assurance Department within two weeks from receipt of the Corrective Action Report Form from the QA Manager.
- Be reviewed by the Director of the State Laboratory Institute and the respective Program Director.

The implementation of recommended corrective actions are documented in section 4 of the Corrective Action Report Form (IPQA071).

Corrective actions are reviewed every two weeks by the State Laboratory Institute Director, Quality Assurance Director and Program Director until all recommended corrective actions are completed. The Quality Assurance Manager coordinates, tracks and posts all corrective actions until all corrective actions are implemented and the follow-up and outcome is complete.

Where the evaluation indicates that the nonconformance or quality problem could recur, an internal audit may be conducted under the direction of the Quality Assurance Manager.

D. VERIFICATION OR VALIDATION

Confirmation that the corrective action plan was effective and did not adversely affect the system is achieved by verifying that acceptance criteria were met, or by validation. This is conducted and documented by the respective department manager in conjunction with the Quality Assurance Manager.

Documentation indicating the outcome of implemented corrective actions, such as document generation and/or revisions, training, etc., is recorded in section 5 of the Corrective Action Report Form by the Quality Assurance Manager.

E. COMMUNICATION

Information is disseminated by the Quality Assurance Manager and the respective department Program Director by circulating the Corrective Action Report, at appropriate stages of the process to those directly responsible for assuring the quality of the process in question.

The respective Program Director and the Laboratory Wide Quality Improvement Committee (LWQIC) review corrective action plans, which have been evaluated for effectiveness.

F. Record Keeping

The Quality Assurance Manager documents confirmation that the information was submitted and documented by respective department Supervisor/Manager, State Laboratory Institute Director, Program Director, Quality Assurance Director, and the LWQIC for review.

All quality records generated from this procedure are maintained according to ISO Guide 17025 4.12 requirements.

6. ATTACHMENENTS

- **Corrective Action Report Form (IPQA071)**

7. APPROVAL SIGNATURES:

REVIEWED:

Date_____ By_____

Date_____ By_____

Date_____ By_____

Authorized to approve:

Harvey George, Ph.D., Quality Assurance Director

Ralph Timperi, State Laboratory Institute Director

Dina Caloggero, Quality Assurance Program Manager